The Scottish Institutional Ecology of Health and Clinical/Medical Research and Key Issues for Scottish Independence

THE SCOTTISH INSTITUTIONAL ECOLOGY OF HEALTH AND CLINICAL/MEDICAL RESEARCH AND KEY ISSUES FOR SCOTTISH INDEPENDENCE

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CONTENTS **Page**

I. Introduction

In the build up to the Scottish referendum on independence, questions are being asked about the relevant opportunities and challenges that may arise for a range of sectors. High on the agenda has been the fiscal and currency options and Scotland's continued place within the European Union. In the context of health, very little has been discussed in terms of what benefits devolution has brought to the clinical and medical research system and its associated healthcare system. In this paper, we provide a preliminary analysis of the institutional ecology of the Scottish health system and key clinical and medical research 'assets' built up since devolution, and which we consider crucial to any informed discussion about the future of Scotland under further devolution or full independence.

For the purpose of this paper, when we refer to 'clinical research' we are limiting the definition to applied clinical studies to test new medicines, technologies, diagnostics and devices in patients or populations through, for example, clinical trials. When we talk about 'medical research' or 'health research', we are broadening the scope of the definition to include basic science and translational studies aimed at improving the body of medical knowledge. Essentially, clinical research is a subset of medical/health research. The 'healthcare system', as distinct from the medical and clinical research systems, represents the point of delivery for healthcare services and the organisations, institutions and actors that are responsible for providing it.

This paper is driven by two key questions. First, what does a fully devolved healthcare system and partially devolved medical and clinical research system mean in practice, and what have been the social, economic and clinical challenges and opportunities engendered by devolution? Here, we want to identify and better understand the key institutional assets and unique selling points in Scotland that have been used to drive a particular health and wealth policy agenda. Second, what do different professionals and key stakeholders (academic researchers, NHS directors, research funders and commercial organisations) see as the potential benefits of full independence or further devolution, and what do they feel may be lost for clinical and medical research, society, economy and public health?

A key message from our work in this area is that the Scottish healthcare system and the clinical and medical research systems are very much interdependent, and the complex institutional ecology that has evolved since devolution will have a significant impact on how the benefits and limitations of independence will be realised and distributed. So far the debate about independence has focused very much on health and social care, but the Scottish system and its quality depends hugely on its medical and clinical research base. This paper addresses this important part of the independence debate.

The data informing this paper was derived from 3 key sources. First, policy documents and secondary data on how healthcare and research needs and priorities have been identified and facilitated under a fully devolved healthcare system and a partially devolved research system were analysed, in order to help us provide a snap shot of the institutional ecology and landscape of the health ecosystem (comprising both research and healthcare). Second, 15 semi-structured interviews with key professional stakeholders (academic clinical scientists, NHS R&D directors and managers, charities, funders and commercial organisations) were used to gather a range of views on

devolution and potential independence. Third, we collected additional data from a roundtable workshop involving a further 12 further key stakeholders working in the Scottish healthcare and clinical/medical research communities to receive feedback on our findings and gather further views on different scenarios for independence.

The paper is structured as follows. In the following section, we identify and briefly describe the key institutions and organisations in the healthcare and research systems and draw out their relevant interconnections in both Scottish and broader UK contexts. In section 3, we then explore the emergence of the health and wealth policy agenda that has developed over the past decade and that has shaped both the healthcare and clinical and medical research systems. In section 4, we critically reflect on the Scottish White paper on independence and its assumptions about healthcare and research. In section 5, we address a number of key themes that emerged from our interviews and workshop on how devolution and potential independence may shape the clinical and medical research capabilities and healthcare systems in both positive and negative ways. We conclude by outlining some key discussion messages that need to inform the referendum debate.

II. Scottish Healthcare and the Institutional Ecology of Medical and Clinical Research

Since devolution, Scotland has presented itself and its population (in policy documents and through the media) as a healthcare research asset for medical and clinical research, and particularly for what has become popularised as translational research. This was partly a consequence of adopting a broad life science strategy in 2005 as a strategic policy[1], as well as the realisation that direct healthcare benefits could be accrued from investment in basic medical research, clinical studies and general research infrastructure. With a range of interesting diseases to study (and well established disease and research networks), a stable and localised population; and a substantial base in academic medicine, it was felt that Scotland could exploit existing competencies, build further capacity and enjoy a competitive advantage in both clinical and medical research. For example: a series of policy initiatives and adoption of new approaches have created a broad range of disease registers (that are well integrated and managed); population wide genomic studies, such as *Generation Scotland: Scottish Family Health Study*[2], improved governance through the coordination of research and ethical approval processes; and the capacity to better integrate academic and clinical activities and potentially translate them into clinically and economically valuable products.

This clinical/medical research and healthcare systems, and the particular institutional ecology that has developed since devolution, covers a broad range of the commercial and public sector research and academic base, as we set out below.

[1] See Lyall, C. (2005) 'Scotland's Science Strategy: An exercise in concurrent power?', Scottish Affairs, 52, pp. 51-70

[2] See http://generationscotland.org/index.php?option=com_content&view=article&id=14&Itemid=14 and Smith, B. et al (2006). 'Generation Scotland: the Scottish Family Health Study: A new resource for researching genes and heritability.' BMC Medical Genetics, 7, 74

Public Healthcare and the Major Clinical and Medical Research Institutions

NHS Scotland: This represents the fully devolved Scottish healthcare system, with funding from the Scottish Government Health and Social Care Directorates. NHS Scotland consists of 14 regional NHS boards, 7 Special NHS Boards and a public health body.[3]

Healthcare Improvement Scotland[4]: Formerly NHS Quality Improvement Scotland, this special NHS board is responsible for 'delivering high quality, evidence-based, safe, effective and person-centred care, and scrutinising services to provide public assurance about the quality and safety of healthcare'. It provides various reports on evidence-based healthcare and best practice guidance.

Scottish Medicines Consortium (SMC)[5]: SMC provides advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of all newly licensed medicines, new formulations of existing medicines and new indications for established products (licensed from January 2002). Its remit excludes the assessment of vaccines, branded generics, non-prescription-only medicines (POMs), blood products, plasma substitutes and diagnostic drugs. SMC also has a horizon scanning function; providing financial and service planning within NHS Boards through the provision of early intelligence on new medicines in development. SMC essentially performs for Scotland the functions of the National Institute of Clinical Excellence (NICE) in England.

NHS Research Scotland (NRS) [6]: NRS is a partnership involving the Scottish NHS Boards and the Chief Scientist Office (CSO). Its aim is to ensure that NHS Scotland provides the best environment to support clinical research, so tends to be focused on the applied parts of medical research that will have a direct impact on patient care. This is achieved through the application of best practice and processes that can support efficient working, as well as providing and managing the infrastructure and policies required for supporting all research undertaken within the NHS. The CSO distributes all NRS funding. NRS has also contributed to the life sciences sector in Scotland, particular where it has been focused on its translating basic research into clinical products. One example cited as a success in this context is the system of coordinated approval for research, operated through the NRS Permissions Coordinating Centre. This was seen as a means to improve efficiency and reduce cost in the development of clinical studies, which is considered by many to be a major advantage of doing research in Scotland. NRS operates in 4 regional nodes and is overseen by the NRS Strategy Board, which comprises CSO representatives, and the R&D Directors of the 4 Boards, which lead the regional nodes.

National Institutes of Health Research (NIHR)[7]: The NIHR was established in April 2006 and commissions and funds NHS research throughout the UK, although in practical

[3] See http://www.scotland.gov.uk/Topics/Health/NHS-Workforce/NHS-Boards for further information.
[4] See http://www.healthcareimprovementscotland.org/welcome_to_healthcare_improvem.aspx
[5] http://www.scottishmedicines.org.uk/Home
[6] http://www.nhsresearchscotland.org.uk/
[7] http://www.nihr.ac.uk/Pages/default.aspx

terms it is very much focused on England and Wales. Its vision is to 'improve the health and wealth of the nation through research'.[8]

Chief Scientist's Office (CSO): The CSO supports research initiated by the research community in Scotland and advises the Scottish Government on how research contributes to improvements in health and healthcare. We discuss the CSO in more detail later.

Scottish National Blood Transfusion Service (SNBTS): This is Scotland's national blood transfusion service, which also has a significant research element and in many respects it operates like a not-for-profit biotechnology company, unlike national services in England and Wales. It is, therefore, a key Scottish asset.

Scottish Medical Schools/Major Research Universities: Edinburgh, Glasgow, Aberdeen, Dundee and St. Andrews are the 5 major research universities in Scotland and represent the major centres of both medical and clinical research and linkages/partnerships with the NHS. Strathclyde and Heriot-Watt universities also have world-class pharmaceutical and technological research with medical and health impact.

Scottish Health Innovations Ltd (SHIL)[9]: SHIL (established in 2002 by NHS Scotland and Scottish Enterprise) is essentially the technology transfer organisation for NHS Scotland. It was set up to protect and develop new innovations from healthcare professionals. SHIL also manages a fund to support NHS adoption of new technologies/developments originating within the NHS in Scotland, and is very much concerned with ensuring clinical studies in particular benefit Scottish Patients.

Clinical Research Facilities (CRFs): There are 7 CRF facilities in total within Scotland (two in Edinburgh, two in Glasgow, with others in Dundee, Aberdeen and the Highlands) providing various levels of support for and expertise in clinical research.

Key Funders

Medical Research Council (MRC): UK-wide funder of medical research, representing a major source of income for Scottish researchers and providing key clinical infrastructure.

Biotechnology and Biological Sciences Research Council (BBSRC): UK-wide funder of the life sciences, some of which may fall within the boundaries of medical research.

Wellcome Trust: Major charitable funder of medical research throughout the UK. Unlike other medical charities, the Wellcome Trust does not rely on donations and is a significant contributor on par with the Research Councils UK (RCUK).

Scottish Funding Council (SFC): Formed in 2005, the SFC is a national, strategic body responsible for funding teaching and learning provision, research and other activities in Scotland's higher education institutions.

[8] See NIHR annual report for details on key activities: http://www.nihr.ac.uk/files/Publications/NIHR%20Annual%20Report%202011-12%20final.pdf
[9] http://www.shil.co.uk/

Technology Strategy Board (TSB): As the UK's major innovation agency, TSB helps business translate new science and technology into commercially viable products. It has funded a great deal of life science research, especially in the area of regenerative medicine (most recently with the establishment of the Cell Therapy Catapult). Delivery is via firms with the NHS and academic institutions as collaborative partners. Scotland is also a sub-contractor in some non-Scottish projects, so there is a great deal of cross-border activity.

Government

Scottish Enterprise (SE): SE is Scotland's economic development agency and has a significant life science division, which develops strategy and invests in the life science sector. Health related life sciences are incredibly strong in Scotland, and much of the support is aimed at translational medicine. SE is primarily a facilitator, but there are examples of direct intervention in terms of strategic support, such as the Translational Medicine Research Collaboration (TMRC)[10], Generation Scotland, SHIL, Biocity and BioQuarter.

Major Commercial CROs

Although there are over 50 small CROs in Scotland, the major firms that represent important clinical research assets include:

Quintiles: A large contract research company that provides clinical research services for biotech and pharmaceutical firms internationally.

PPD Development: A leading global contract research organisation that provides discovery, development and post-approval services, as well as compound partnering programmes in drug development.

Charles River Laboratories: A US contract company providing preclinical and clinical services, which has a presence in Scotland.

Onorach Clinical: A leading clinical trial CRO.

Major Networks (Scottish and UK-wide)

There are a number of important clinical research networks within Scotland, with varying degrees of interaction and overlap with UK wide bodies. They include:

Scottish Clinical Research Networks – Management of the Scottish Clinical Research Networks is coordinated by the CSO, which has encouraged NHS Scotland and the Scottish clinical academic research community to work to expand clinical research activity in a collaborative way. There are seven Networks in Scotland (including existing Networks in cancer):

[10] Mittra, J. (2013) 'Exploiting Translational Medicine through Public-Private Partnerships: a Case Study of Scotland's Translational Medicine Research Collaboration (TMRC)', In Mittra & Milne (eds) *Translational Medicine: The Future of Therapy?* 2013, Pan-Stanford: Singapore, pp. 213-229

- Dementia Clinical Research Network
- Scottish Diabetes Research Network
- Scottish Medicines for Children Research Network
- Scottish Stroke Research Network
- Scottish Mental Health Research Network
- Scottish Primary Care Research Network
- Scottish Primary Care Research Network (SPCRN): Established in 2002, SPCRN to facilitate national research activity in primary care, undertaking projects with other Scottish Networks and colleagues in England.

Research outwith the above topics or the area of Primary Care is supported through general NRS Infrastructure funding provided to Scottish NHS Boards. Other UK-wide networks include:

Experimental Cancer Medicine Centre Network (ECMC): Launched in October 2006, the ECMC is jointly supported by Cancer Research UK and the health departments for England, Scotland, Wales and Northern Ireland, providing a total of £35 million over five years to fund a network of Experimental Cancer Medicine Centres across the UK.

NHS Clinical Research Network (NIHR CRN): As part of the National Institute for Health Research, NIHR CRN provides infrastructure that allows high-quality clinical research to take place in the NHS (England and Wales).

Major Charities

Apart from the major funding provided by the Wellcome Trust, described earlier, major charities with a presence in Scotland include Cancer Research UK (CRUK), Chest, Heart and Stroke; Diabetes UK, Stroke Association; Alzheimer's Society, the Genetic Alliance and the British Heart Foundation. The charitable sector is a major source of funding for the more applied clinical studies, and we discuss this in more detail later in the context of independence.

This all adds up to a wide range of public and private institutions, organisations and networks that operate primarily within Scotland, or are enmeshed within broader UK based networks. The result is a complex and evolving institutional ecosystem[11], with various strategies, policy initiatives, dependencies and levels of interconnectedness. The sustainability and success of medical and clinical research, and the impact of this in more downstream healthcare delivery, is therefore dependent on a supportive health ecosystem and well-functioning and coordinated institutional assets and organisational resources.

[11] For an account of ecosystems theory see, Adner, R. & R. Kapoor. (2010) 'Value creation in innovation ecosystems: how the structure of technological interdependence affects firm performance in new technology generations', *Strategic Management Journal,* 31: 306-333.

III. Scotland's Health and Wealth Policy Agenda and the Shaping of the Institutional Landscape

Over the past ten years, the link between support for medical and clinical research and future economic benefit has become more prominent in Scottish policy discourses. Health and wealth have become more tightly coupled as part of a broad life science strategy, which is detailed in Scotland's most recent Life Sciences Strategy Report, 2011.[12] The report states:

> 'Our ambition is to double the economic contribution of Life Sciences to the Scottish economy by 2020. Part of the future vision presented is that the National Health Service (NHS) moves centre stage as a key customer for Scottish Life Sciences businesses and a pivotal stimulator of innovative products and services.'

In this context, there are three key elements - Health, Research and Economic Impact/Benefit, which are represented by a number of key institutions. We will now discuss each in turn in order to develop a deeper understanding of the institutional ecosystem and health/research strategies and policies that have been undertaken post-devolution within Scotland. It is only with a full understanding of this institutional landscape that we can begin to address the key questions around the functioning of healthcare and clinical/medical research systems under the scenario of independence.

NHS Scotland: The Healthcare Element, with Some Research Capacity

NHS Scotland's activities within the broader UK NHS context are relatively autonomous. Indeed, unlike the clinical and medical research systems, healthcare provision through NHS Scotland is fully devolved and able to organise and deliver its services in line with particular Scottish needs and requirements (including a small NHS clinical research element). In the context of the NHS, research (both clinical and medical) is quite a marginal activity, and in those limited cases where it is explicitly supported it is very much focused on applied rather than basic research; essentially clinical studies for new drugs, devices or diagnostics. To illustrate the marginalisation of research, the Scottish NHS Chief Executive's Annual Report 2012[13] hardly mentions research, in the conventional sense. Other priorities around healthcare delivery are emphasised, including patient waiting times, delivery of key services and patient related outcomes. When research is mentioned, it tends to be focused on more downstream and applied activities such as assisted living. For example, the Delivering Assisted Living Lifestyles at Scale (DALLAS), a competition scheme that has funding from Scottish Enterprise (£5m), the Technology Strategy Board and the National Institutes for Health Research (£18m), was launched in 2011. It aims to establish five 'communities' of 10,000 people (one community will be in Scotland), to demonstrate how assisted living technologies and services can be used to improve care. It talks about 'unlocking new markets in social

[12] Life Sciences Scotland (2011) 20:20 Vision: Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health, http://www.lifesciencesscotland.com/media/14388/lss-strategy-2011.pdf
[13] NHS Scotland (2012) *Chief Executive's Annual Report,* November 24, 2012, The Scottish Government, http://www.scotland.gov.uk/Resource/0040/00408794.pdf

innovation', so is very much rooted in social technologies to improve patient wellbeing.[14] Although this helps to build a more user and patient-oriented, less science-push research approach, it is very far removed from the basic medical research and the conventional clinical research with which Scotland has historically had strong capabilities and markets to international collaborators.

Clinical research (but less early stage and basic medical research) within NHS Scotland is funded predominantly through NHS Research Scotland (NRS) (with funding distributed from the CSO). The priority here has mainly been to build infrastructure to support clinical research. In practice, this means people and processes, particularly research nurses and managers for clinical trials (mainly non-commercial as we shall see later). In addition, Quality Improvement Scotland is tasked with supporting high quality, evidence-based care, which is very much focused on healthcare rather than clinical or medical research.

The Chief Scientist's Office: The Research Element

The Chief Scientist's Office (CSO) is essentially the central research funding arm for the NHS and represents Scotland's core public research asset. The CSO 'supports research initiated by the research community in Scotland and advises the Scottish Government on how research contributes to improvements in health and healthcare.'[15] The CSO's current research strategy (2010-2014) is outlined in its report 'Investing in Research: Improving Health'[16], which outlines key funding priorities for both broad population health initiatives and skills/capacity building.

The CSO has an annual budget of approximately £69m (2013/2014), and on its website lists the following as key activities and priorities:

- Funding high quality research relevant to NHS Scotland on the recommendation of the Research Advisory Committee. At any one time the CSO funds around 190 research projects.
- Supporting research in NHS Scotland through the NRS (NHS Research Scotland) partnership.
- Contributing to funding of research awarded through the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC).
- Offering a number of training fellowships to improve the R&D skills base and fuel the development of evidence-based practice.
- Building and implementing a Health Research Strategy for NHS Scotland.
- Promoting the dissemination and implementation of research findings.
- Encouraging strong research ethics appraisal and research governance.
- Supporting a number of research units across Scotland.
- Participating in a number of Scottish and UK-wide health research initiatives.
- Including public representation in our decision making processes.

[14] See http://webarchive.nationalarchives.gov.uk/20130221185318/www.innovateuk.org/content/competition/dallas-delivering-assisted-living-lifestyles-at-sc.ashx
[15] See http://www.cso.scot.nhs.uk/ for more information
[16] CSO (2009) *Investing in Research: Improving Health*, The Scottish Government 2009, http://www.cso.scot.nhs.uk/Publications/research.pdf

- Responsibility for policy relating to intellectual property arising from research in NHS Scotland.

The CSO's modest budget also appears to be very focused on infrastructure, but funding key positions and co-funding some research and dissemination activity. Indeed, one might argue that it is set up institutionally and strategically to contribute to broader clinical translation. Translation here is about linking basic research to clinical outcomes and ensuring knowledge, technology and expertise is better coordinated and supported across the whole innovation pathway from bench to bedside.[17] The CSO conducts a great deal of partnering activities with the Medical Research Council (MRC), the Research Charities Development Trust and some of the NHS boards in England. Overall, the CSO's work is rather diverse and covers a broad landscape of activity in both Scottish and broader-based UK networks and collaborations.

The CSO is structurally organised around four key health boards or nodes - Glasgow, Edinburgh, Dundee and Aberdeen, below which are a series of tiers (for example, Fife would be a tier below Dundee), although the structure of these networks is currently under review. Each individual board has its own research infrastructure and research capacity, and that extends to some specialist boards, such as the Golden Jubilee Hospital in Clydebank, and also units such as the Scottish National Blood Transfusion Service. The latter, as we stated earlier, is quite a significant player in terms of research activity so constitutes an important research asset for Scotland. This includes applied clinical research as well as basic medical research. SNBTS has a particularly important research role in regenerative medicine and has historically contributed a great deal to innovation in blood and related products. It is, therefore, institutionally very different from its English and Welsh counterparts. There is some research activity in Liverpool as part of the blood transfusion service, but it is at a very different scale and scope from SNBTS. SNBTS benefits from both its location near major clinical and medical research assets in Edinburgh, and the fact that it is a national service only responsible for servicing a population of 5-6 million, unlike its English counterpart, which must spread its resources much more thinly.

In addition to these two main coordinators of healthcare delivery and clinical/medical research, there are a variety of charities, commercial organisations and major research universities contributing in various ways to non-commercial and commercial clinical research activities, which we described earlier.

Economic Benefit, Clinical Resources and the Building of a Life Science Strategy and 'Living Lab'

From an economic point of view, clinical resources can be considered a prime focus to develop infrastructure and promote collaborative activities both within Scotland and with UK and International partners, including with commercial organisations. At present, there may be a missed opportunity to more closely link the commercial and public research assets with expertise and know-how, so as to strengthen the overall national clinical

[17] See Mittra, J (2013) 'Repairing the 'Broken Middle' of the Health Innovation Pathway: Exploring Diverse Practitioner Perspectives on the Emergence and Role of 'Translational Medicine', *Science and Technology Studies,* 26 (3): 103-123

research asset and innovation ecosystem. There are a large number of large Contract Research Organisations (CROs) located within Scotland (for example Quintiles and PPD), which could constitute an important part of the institutional ecosystem for clinical research and healthcare delivery. But not a great deal of commercial research in terms of active clinical studies is carried out within Scotland.

In particular, such strengthened links could then be packaged in a way to attract further inward investment into Scotland, which has been part of the Scottish government's strategy, but has not been borne out fully in practice. Indeed, in the past this was thought of as a viable strategy, and a good example of trying to make it happen in practice was the Translational Medicine Research Collaboration (TMRC). The TMRC brought together the key universities and NHS boards, with Scottish Enterprise and a large pharmaceutical company (Wyeth and then Pfizer), to develop translational clinical activities.[18]

Nevertheless, the linking of health and wealth in the context of both NHS Scotland and the broader clinical research infrastructure must be understood in the context of the Scottish Life Science Strategy that was, in a sense, enabled by devolution. There was a life science strategy, or what was originally a biotech strategy, from 1999, which focused on supporting a small and medium sized company sector as part of an evolving biotech cluster and national innovation system (this strategy was actually discussed before devolution and later fed into the Scottish Science Strategy).[19] Scotland's particular approach to building a vibrant life science sector took a number of forms over a long period, from a quite novel and embryonic industrial sector in the late 1990s to one with many diverse firms with great scale and potential for economic and health impact. Scotland's policy and strategic approach demonstrated a high degree of pragmatism in the development of a life science strategy post-devolution, orchestrated by Scottish Enterprise.

More recently, the 2011 Life Science Strategy, which we referred to earlier, took this strategy much further in terms of trying to build innovation capacity and better integrate complementary clinical/medical research assets and healthcare infrastructure, with NRS having an increasingly central role.

Lyall's 2005 article on Scotland's science strategy argues that devolution presented the Scottish Executive with the opportunity to develop an integrated and inclusive approach to research and innovation strategy by 'co-ordinating the roles of policy-makers in different government departments and agencies and involving policy targets across the science base and technology-based industry in the policy-making process.' However, Lyall argues that the model promoted by the Executive continued to be one of 'academic push' (which it still is) rather than 'industry pull', and that the Scottish Executive's 2001 science policy document,[20] from inception to implementation, focused

[18] Mittra, J. (2013) 'Exploiting Translational Medicine through Public-Private Partnerships: a Case Study of Scotland's Translational Medicine Research Collaboration (TMRC)', In Mittra & Milne (eds) *Translational Medicine: The Future of Therapy?* 2013, Pan-Stanford: Singapore, pp. 213-229

[19] Rosiello, A (2007) 'At the Interfaces of Governance and Competence Perspectives: Discussing Organizational Choices in the Scottish Biotechnology Cluster', Technology Analysis and Strategic Management 19 (1) 45-68

[20] Scottish Executive (2001). A Science Strategy for Scotland. Edinburgh, Scottish Executive.

on the public sector and on supporting the science base in Scottish universities, without reflecting sufficiently on the need to develop greater capacity on the demand-side in order to foster a vibrant technology-based economy. According to Lyall, 'this apparent adherence to an out-dated way of thinking about innovation means that Scotland has so far failed to optimise the opportunities offered by devolution in terms of shared policy competences for science and innovation between and within levels of governance and between policy-makers and policy targets'.

Devolution arguably made it easier to develop a national strategy as it provided a degree of autonomy and independence, and almost certainly contributed to the development of research and clinical infrastructure, particularly through some of the NRS activities of the larger health boards. However, there is little evidence in terms of crude numbers to show a strong and persistent link between the health and wealth agenda, nor has there been a clear health and wealth strategy to successfully integrate public and commercial resources and institutional research assets for broader public benefit. Nevertheless, the notion of Scotland as a 'living lab' for medical and clinical research has become prominent as a concept to highlight and potentially market the unique health challenges of Scotland and the related research opportunities that this engenders. We explore the 'living lab' concept in more detail in a related working paper (From 'Sick Man' to 'Living Lab' - The Narrative of Scottish Health Since Devolution: http://innogen.ac.uk/working-papers/889), but it is important to understand this concept as a driver of medical research and specific clinical activities in Scotland.

The notion of a 'living lab' presents Scotland's population as a national resource for both early stage medical research, but mainly downstream clinical studies. The idea is that health outcomes can align more directly with broader economic benefit (particularly in terms of inward investment and promotion of new commercial opportunities). There are a number of factors that make Scotland's population a potential clinical asset:

1. A stable and relatively homogenous population that is quite concentrated and generally willing to participate in research. Also, there are small and concentrated immigrant communities, so it is possible to conduct studies on select ethnic groups in theory, although the numbers are still relatively small.
2. A population where all the major chronic diseases are represented.
3. A country with strong research capacity, record linkage (through the unique Community Health Index – CHI – number) excellent disease registers (5-6 key national research registers, with diabetes the most mature) and tissue banking facilities, although again the numbers are small.
4. Governance and approval systems that are arguably more streamlined and efficient than the rest of the UK.

In terms of infrastructure for the living lab, Scotland is quite well advanced. There are a number of excellent Clinical Research Facilities (CRFs), which are typically specialist centres where patients go to participate in clinical research. They are generally part of a large hospital complex, and the largest of these are described in Box 1.

Box 1: Scotland's Major Clinical Research Facilities

Aberdeen Clinical Research Facility: http://www.abdn.ac.uk/crf/
'The University CRF is suitable for 'ambulatory' clinical research such as population-based epidemiological studies of clinical trials.'

Dundee Clinical Research Facility: http://www.dundee.ac.uk/research/main/technology-transfer/20090112123805/
'The CRC can support and accommodate all phases of clinical trials, including unique and special requirements as per the individual trial proposal. Currently the CRC has over 102 clinical trials running from CRC Tayside and 11 in setup. These trials cover all health spectrums, including Oncology, Diabetes, Cardiovascular, Dental and Haematology.'

Edinburgh (Wellcome Trust) Clinical Research Facility: http://www.wtcrf.ed.ac.uk/Content.aspx?dbid=crf_admin&areaid=999&name=Home&type=Content&oid=1
Embedded in the three main hospital sites in Edinburgh, the CRF provides state-of-the-art facilities to support clinical research. Investigators can apply to use a single CRF site or multiple sites.

Glasgow Clinical Research Facility: http://www.glasgowcrf.org.uk/
Provides clinical research support in terms of the provision of trained research staff, dedicated clinical research space and expertise in the conduct of clinical trials. In conjunction with its partners at the Robertson Centre for Biostatistics, it is also able to offer help with protocol design and statistical and data management support.

Highlands Clinical Research Facility: http://www.centreforhealthscience.com/highland-clinical-research-facility.asp
Supports clinical research in the Highlands of Scotland. It is a state of the art purpose built facility housed within the Highland Diabetes Institute, part of the Centre for Health Science; a 10,000sqm centre of excellence in life sciences. The HCRF is adjacent to the largest hospital in the region, Raigmore Hospital in Inverness. The Highlands and Islands of Scotland offers a unique research environment combining rich research assets in clinical and academic interests, with access to an under researched population, although it is spread out, and high quality support infrastructure.

Beardmore Centre for Health Science at the Golden Jubilee: http://www.beardmorehealthscience.com/
Co-located with the Golden Jubilee National Hospital and the Beardmore Hotel and Conference Centre in Clydebank, near Glasgow, this CRC combines excellence in medicine and healthcare with excellence in conferencing and hospitality, to provide various clinical research support.

In addition to the clinical research facilities, Scotland has a number of specialist competencies, such as imaging and tissue banking, which contribute to the value of the living lab concept in the context of medical research.

Basically, from a 'living lab' point of view, all the key infrastructure and personnel is in place to capitalise for both health and wealth. Post-devolution has brought significant progress in building viable Scottish assets in clinical research and healthcare delivery. The wealth agenda aspect has largely been driven by Scottish Enterprise and the life science strategy, which may well be unique globally. It had three key elements:

- A perhaps marginal focus on spinout companies, through Scottish Health Innovations Ltd (SHIL).
- A resource for securing and managing new collaborations and clinical trials, although in reality very few were actually created.
- A route to procurement for Scottish and international firms wishing to sell to NHS Scotland.

Very few countries have an integrated public health system like the NHS, and Scotland has the additional benefits of electronic patient records and streamlined ethical approval and consent procedures. This is what attracted Wyeth to Scotland when the Translational Medicine Research Collaboration (TMRC) was set up in 2006; a large-scale public-private initiative built on the rhetoric and promise of the living lab.[21]

Institutionally, then, the living lab concept and the infrastructure and facilities built around it are set up to contribute to improved health and wealth in Scotland by driving forward both commercial and non-commercial clinical research and healthcare delivery. There are both opportunities and challenges, however, in fully exploiting and delivering on the promises of the programmes and initiatives set up post-devolution.

IV. Reflections on the Scottish White Paper on Independence

The Scottish White Paper on independence[22] includes a relatively small section on health, social care and the NHS (pages 170-176), as part of a larger chapter on Health, Wellbeing and Social Protection (chapter 4). Like the rest of the document, which is essentially a manifesto for the Scottish National Party, the narrative is very positive in setting out what the government believes are the major benefits that have come with devolution (allowing Scotland to respond to its own national needs), the unique challenges that continue to face Scotland, and the subsequent opportunities offered by full independence. However, the document is weighty in terms of the sheer volume of pages, but rather light on detail. This is perhaps unsurprising when considering the range of issues that are implicated in the independence debate.

On the topic of health, the focus of the document is very much on reassuring the public that access to NHS services will not be significantly affected by a yes vote. As health is already fully devolved, the argument is that most aspects of healthcare delivery will for the most part remain the same. The advantages that devolved healthcare have brought about are clearly set out in the document and represent real success. For example, Scotland has been able to avoid much of the organisational restructuring of the NHS that has taken place in England, and real progress has been made in linking the health boards and joining up health and social care. So while day-to-day management of the NHS and access to services will remain unchanged, the Scottish government claims that independence could facilitate a transformation in the environment within which the NHS operates so that health inequalities (which are a significant and growing problem) can be tackled more effectively. One positive benefit outlined is that Scotland would be able to negotiate directly with the pharmaceutical industry on the price of drugs, rather than

[21] See Mittra, J (2013) 'Exploiting Translational Medicine through Public-Private Partnerships: a Case Study of Scotland's Translational Medicine Research Collaboration (TMRC)', In Mittra & Milne (eds) *Translational Medicine: The Future of Therapy?* 2013, Pan-Stanford: Singapore, pp. 213-229

[22] The Scottish Government (2014) *Scotland's Future: Your Guide to an Independent Scotland,* http://www.scotreferendum.com/reports/scotlands-future-your-guide-to-an-independent-scotland/

doing this through UK bodies. These are all laudable goals, and the positive initiatives that have been implemented under devolution suggest that there could be further benefits from independence.

However, the document says very little in terms of medical and clinical research, which as we have described is only partially devolved. This is interesting, because research (particularly early stage medical research, but also clinical trial studies in niche areas) is a key strength in Scotland and there are clear links and contingencies between the research and the health system. Scotland has been pioneering in clinical and medical research, and has built up significant assets and capabilities, particularly in the life sciences. The question is how, and to what extent, independence would impact on the research systems and the institutional ecologies that have been evolving since devolution. There are clear opportunities for building this research capacity under independence, for example adopting new specialised strategies that meet specific health needs within Scotland, but such approaches are not mentioned in the White Paper.

There are also a lot of uncertainties about the medical research system and how it would be funded and governed. The White Paper states that under independence Scotland would seek to continue contributing to and drawing from UK research council funding within a single research area, although there is no guarantee yet that the rest of the UK would support this. Indeed, the UK government explicitly stated that Scotland would not be able to draw on RCUK funds. Again, there is no real detail in the Scottish White Paper on what the options might be (only that Scotland would pay into the system based on population size). Furthermore, charities, such as the Wellcome Trust, have expressed concern about contributing to fund research in an independent Scotland[23], so one cannot assume things will continue as they are currently. On regulation and governance, the White Paper states that Scotland would continue to contribute to regulatory bodies such as the MHRA for approval of drugs and not set up its own regulatory bodies, but again this is something that would have to be agreed and negotiated. It cannot simply be taken for granted.

Overall, the White Paper clearly sets out what the current Government thinks are the key benefits for Scotland of a yes vote, but on the important issue of research and its relationship to healthcare there are a number of outstanding questions that need to be answered before an informed decision can be made. In particular, the funding arrangements need to be firmly established, scenarios for a range of different contingencies outlined, and a clear strategy for developing research under independence elaborated. There are likely to be many new opportunities with independence, but there are also multiple challenges and barriers that cannot be ignored. The White Paper also reflects the general foci of debate in the lead up to the referendum in associating health with social policy and social care, and focusing on the delivery side of health rather than the research side, which remains a marginal issue.

[23] Wellcome Trust Draft Response to House of Commons Business, Innovation and Skills Committee: The Implications of Scottish Independence for Higher Education and Research, June 2013.

V. Healthcare and Clinical/Medical Research in Scotland: Key Issues Relevant to Devolution and Independence

The Important Link between Healthcare and the Medical and Clinical Research Systems

The 2010 Care Quality Strategy for NHS Scotland report[24] outlined some of the key economic benefits of a healthy working population (more people in the workforce, fewer sick days and higher productivity) and efficient health service (with performance measures that involve patients). In many ways, it builds on the 2007 'Better Health: Better Care Action Plan' launched by the Scottish Government.[25] The 2010 report stated:

> 'The Healthcare Quality Strategy will ensure that we maximise the contribution of NHS Scotland to the wider Purpose of the Scottish Government to create sustainable economic growth and opportunities for everyone in Scotland to flourish.'

The report also contains what might be considered distinctively Scottish elements, especially in terms of governance with a focus on alcohol and pricing and a call for greater involvement of local government in social care. In the latter case, there are a number of developing health and social care partnerships in Scotland. The aim is to link the healthcare system and the involvement of local councils to tackle deprivation and healthcare for the elderly and disabled. Questions are being asked about the joining up of health and social care initiatives strategically to benefit the Scottish economy, and in this context there is a clear focus on local markets and contingencies. There has been emphasis within the life science strategy on Scottish companies, or Scottish-based companies, tapping into local markets and selling predominantly within Scotland. However, this has proved difficult in the context of healthcare, since organisations like the NHS in Scotland (as well as the rest of the UK) are not early adopters of new technologies.

These measures are very much in line with the White Paper in their emphasis on low-tech solutions to public health. Nevertheless, there is a clear consensus, reflected in the accounts of our interviewees and workshop participants, of a direct and positive link between the maintenance of a strong medical research system, particularly clinical research studies, and the quality of healthcare delivered to local patients in the clinics where this research is located. As one senior academic stated:

> *There's lots of observational data, obviously there's no good experimental data on it, but factors of 10:1 are generally quoted of the value that accrues to health systems by having research going on. Patients get better care that are taking part in research and newer, better things get brought into health systems fast as a result of research, you get more skilled workers because research is going on rather than it just being a service commitment … in England, when they were deciding where to put the new medical schools and the research activity, they put*

[24] Scottish Government (2010) *The Healthcare Quality Strategy for NHS Scotland,* May 2010 http://www.scotland.gov.uk/Resource/0039/00398674.pdf

[25] NHS Scotland (2007*) Better Health: Better Care Action Plan*, Scottish Government 2007 http://www.scotland.gov.uk/Resource/Doc/206458/0054871.pdf

> *them in areas where there was historically poor standards of service.* (Senior Academic Clinician 1)

Another senior academic stated that areas with significant research capacity would attract the highest quality doctors and nurses who will not only drive the research agenda but also deliver quality healthcare to patients. Policymakers, therefore, ignore the link between healthcare and the medical and clinical research systems at their peril. Indeed, one interviewee claimed that patients who do not have access to a university hospital are disadvantaged. As such, healthcare in the Highlands and Islands, for example, may not be as good as that within the major university cities, because there are no teaching hospitals and research centres of excellence.

The Impact of Devolution on Devolved Health and Partially Devolved Research

The question then is, what has devolution ultimately delivered for Scotland in the context of its fully devolved health system and the partially devolved research system that have co-evolved? And, what can Scotland potentially do better, faster and cheaper with its particular set of institutional assets? With respect to research and healthcare organisation, there was a general sense from our workshop respondents that devolution has allowed Scotland to avoid the major England NHS restructuring, which was also stated in the Scottish Government White Paper as a key benefit. Scotland has in many ways been able to differentiate itself and its clinical assets and operate a relatively joined up health system with efficient and streamlined governance structures. As one NHS R&D Director stated when interviewed:

> *Scotland works very well together in a way that England doesn't and probably can't, but whether or not that's an impact of devolution I don't know because Scotland is reasonably small and it can work like that, and it should work like that given its size … The changes in the ethics committees came about for reasons other than that, they had to happen and they were very important and they impacted on rates of approval [for clinical studies] and things like that, but I don't know whether you could attribute them to devolution.* (Senior NHS R&D Manager 1).

Another NHS representative stated:

> *All the health boards in Scotland have grouped together and we have now have come together as NHS Research Scotland. So we're now pulling our weight as the whole country rather than individual health boards. We can't really do that on a UK basis because there's so many different trusts and boards in the UK.* (Senior NHS R&D Manager 2).

There are clear advantages of scale in Scotland that have been exploited to improve the overall health system, according to many respondents. However, this was not necessarily a direct consequence of devolution, but would have perhaps happened in any case. We could say this about almost all of the unique selling points of the Scottish system, such as electronic patient records, the institutional ecology built around the living lab concept, and the setting up of the research networks. As one representative from a CRO explained, Scotland is in many ways an easier vendor or supplier of clinical research services because everything is smaller, faster and more efficient. However,

what devolution may have done is speed up some of the changes in organisational structure and policy to suit the specific needs of Scotland and, most crucially, allow the NHS to avoid some of the more radical neoliberal structural changes taking place south of the border. This, according to a senior academic clinician, has *'helped us to maintain productivity within the healthcare sector that we had before simply because we haven't been party to the large experiment that's taking place south of the border'* (Senior Clinical Academic 2). Therefore, stability in healthcare infrastructure is here presented as a key benefit of devolution. However, as another senior clinician opined at the workshop, there has been a gradual decline in the average patient experience across the whole of the UK, largely due to investment declining in real terms and the overly bureaucratic and managerial nature of the system. Scotland may have a better health system than the rest of the UK, but that is not to say it is the best system it could be, or that major restructuring is not now necessary to generate real improvement in healthcare outcomes.

Interestingly, representatives from the charitable sector tended to have a more positive view of the impact of devolution on the Scottish health system. One stated that *'it's allowed Scotland to tackle issues that it sees are pressing, health deprivation, health issues in the West coast and all the rest of it, and I think also in the hard to reach communities. In terms of focusing the mind it has done quite well'* (Representative of Major Research Charity 1).

In summary, there appears to have been many changes in Scotland, some but not all directly linked to devolution, which have enabled a particular health and research system to evolve and deal more directly with Scottish issues. On the one hand, there have been policies, such as the smoking ban and health and social care initiatives, to tackle specifically public health and related social deprivation. On the other hand, there have been well organised research networks and governance structures to enhance clinical research capabilities and, by linking with NHS resources and assets, provided an opportunity to capitalise on the broad health and wealth agenda. The question now is how has this been exploited in practice and would independence open up many more opportunities?

Relationship between Commercial and Non-Commercial Clinical Research Studies in Scotland

In terms of clinical research (applied clinical studies such as clinical trials), the CSO, as already described earlier, is the key driver attempting to sustain Scotland's research performance, build capacity, exploit translational research and build the knowledge base to enhance NHS Scotland. The difficulty for the CSO, in terms of performance, is that metrics are ambiguous for non-commercial research. There is a dearth of reliable data to get a real sense of what is going on. We do, however, have some limited data from NHS Scotland on commercial and non-commercial clinical trial activities, which is important for understanding the economic and strategic priorities and implications for independence.

The comparative data on commercial and non-commercial research[26] shows that non-commercial research in Scotland is the largest by a factor of more than 10. In terms of public expenditure on health-related research (of which clinical trials are a significant

[26] Source from an unpublished NHS Scotland document

portion), based on 2012 figures, more than 11.5% is spent in Scotland, which represents 8.5% of the UK population.

Scotland attracts a disproportionate level of RCUK public funding for research, but a great deal of clinical research in NHS Scotland is supported through the CSO infrastructure budget, which equates at £45m in total to £9 per head in Scotland, £800m to £16 per head in England, and £32m to £11 per head in Wales. So England and Wales invest more in clinical research per head of population than Scotland. This infrastructure budget includes spend directly on clinical studies (which is probably quite small), but also research positions, tissue banks and governance processes. The majority of the budget is spent on staff, facilities, networks and governance – or what might be termed 'enabling activities'.

If we move down to the level of the NRS, there are a number of operational clinical research units in Scotland. There are the six CRFs that we have already described, but there are also significant medical research assets, such as tissue acquisition services and biorepositories, a research-imaging platform, and 'Safe Havens' health informatics research (SHIP). The Safe Havens are most developed in Dundee, which has built up staff capacity in arrange of activities. The idea of a safe haven is that researchers can go to them to seek information on potential recruits to clinical studies anonymously, and the Safe Haven will process the data to provide, for example, indication levels and number of eligible patients. The idea is to create economies of scale in health informatics and recruitment.

In terms of commercial contracts for clinical research studies, there is not a significant level of commercial activity generating a lot of value for Scotland, even though the 'living lab' concept is partially based on the notion that Scottish resources and institutional infrastructure are an attractive investment proposition.

It is not entirely clear why the commercial share of clinical research expenditure is so small. One could argue that non-commercial research is more closely associated with direct healthcare benefits whereas commercial clinical research studies are simply viewed as a good, but not essential, source of additional income. But, it also likely has something to do with limited amount of time, limited number of patients on particular studies, and higher levels of non-commercial work, because the work can be more easily published, which affects the incentives of researchers. So, the 'living lab' concept is essentially built and focused on the further development of non-commercial clinical activities, of which Generation Scotland is a prime example that we discuss in another working paper (From 'Sick Man' to 'Living Lab' - The Narrative of Scottish Health Since Devolution: http://innogen.ac.uk/working-papers/889). Commercial activities tend to be focused on novel products that must meet regulatory requirements, and with companies looking for speed and low cost, this means trying to minimise the level of sophistication as much as possible. Indeed, in Scotland, these tend to be Phase 2 or Phase 3 trials as there is not a great deal of capacity to conduct Phase 1 trials – these 'first in human safety' studies require very specialised units. The data here, then, does not really fit in with the high-tech and sophisticated living lab concept that was a key element in the health and wealth agenda. Also, commercial companies, according to one of our workshop participants, do not view Scotland as doing anything particularly different than the rest of the UK, in terms of types of studies conducted. Scotland differs in the higher costs due to the multipliers set by the Scottish government, which some believe are too

high. Having said that, some of our interview respondents did state that Scotland has world-class capabilities in certain niche areas, such as diagnostics, devices and gene therapy trials that are perhaps a real and significant selling point.

Our interview respondents and workshop participants generally revealed a number of different and salient views about the relationship between commercial and non-commercial clinical studies. For some, the commercial side was not considered of particular strategic importance, but others felt that Scotland was no pursuing the commercial side as aggressively as it should, and this related largely to the cultural attitude towards commercial research within the NHS. One R&D manager in the NHS, who did value commercial studies, stated:

> *There is a thought out there with consultants that commercial studies are somehow less important than academic studies, and by coming from an academic research background myself I understand that opinion … however, commercial studies will pay for the, if you're income generating a significant amount of money from commercial studies, you can maintain a research nurse, and the research nurse is then able to coordinate your non-commercial activities … But there is definitely a cynical attitude in the NHS towards commercial research.* (Senior NHS R&D Manager 2)

This view was shared by many of our workshop participants and other interviewees who felt that the value of commercial studies was underappreciated. Another R&D Manager, for instance, stated that there has not been a significant increase in commercial studies over the past few years and Scotland could have worked harder to generate more income from commercial studies. One workshop participant suggested the NHS needed to think 'outside the box' when it comes to commercial work and believed that all hospitals should have a dedicated commercial unit, which could drive a research culture in the NHS. Dundee is doing this already to an extent and recognising that research links are a good way to drive up standards of healthcare delivery.

However, patient recruitment is a continuing challenge for both commercial and non-commercial clinical studies in Scotland, which related in many ways to the size of the population and the scale of the research infrastructure. Scotland is simply not large enough to be a really big player in international commercial trials and, like the rest of the UK, often fails to meet recruitment targets. A policymaker that was interviewed suggested that it is easy to sell the academic innovation in Scottish life sciences to international companies, but selling the idea of Scotland as a place to do large clinical trials is much more difficult. Nevertheless there may be opportunities to differentiate and become much more specialised under independence.

Funding of Medical Research and the Concept of a Single Research Area

Perhaps the most important uncertainty around the future of medical research (basic and applied) and clinical research support in Scotland post-independence relates to funding, and our interviewees and workshop participants cited this as a key concern, particularly the academics who feared that RCUK money would no longer be available to fund medical research. Government funding is not the only source of support for research; there is a large charitable sector that has to consider how their operational strategies

might be impacted by independence, as well as commercial organisations thinking about where they should invest.

Representatives from various charities (large and small) that we interviewed all stated that their mission is essentially to fund the best science. Most stated that they spend more in Scotland than they raise in Scotland, but they do this because there is excellent science located here. So, as previously discussed, the narrative of Scotland being a great place to do medical research, and conduct clinical trials, is not simply hype. It does have a significant impact on attracting investment. However, many of the charities believed that if Scotland left the UK it would have to be treated like all other non-UK countries. In its draft response to the House of Commons Business, Innovation and Skills Committee: The Implications of Scottish Independence for Higher Education and Research, the Wellcome Trust stated that its eligibility criteria for funding Scottish institutions would have to be reviewed if Scotland decided to become independent. Wellcome has provided over £600m in competitive funding to clinical and medical researchers in Scotland over the past 10 years, including major contributions to the Universities of Edinburgh and Dundee (£100m each), as well as research within the NHS and national informatics programmes such as SHIP. So across all types of research within the realm of health, Wellcome has been a significant contributor. Although Wellcome did not state a firm position on how it would treat an independent Scotland, it suggested arrangements, such as that which applies to Ireland might need to be considered (Wellcome funds some research in Ireland, but the Irish government must pay 50% of any awards for medical research).

One of our interview respondents stated that in many cases, particularly for basic medical research, but also translational research, charities tend to take their lead from research council priorities. This is particularly evident in the case of rare and genetic diseases. The respondent then stated that there would be some concern from charities if national prioritisation and the way research councils worked together changed as a result of independence. This respondent stated:

> *If the organisations in the independent Scotland were aligned operationally with the rest of the UK, if the priorities worked well in terms of research prioritisation and the funding of infrastructure was aligned, and if funding support were maintained [government top up to charitable funding of direct costs] in an independent Scotland in a consistent way then I don't think charities would find it an issue. But I think all those things are uncertain.* (Chief Executive of Major Charity)

The uncertainty about Scottish policy post-independence means it is not yet clear whether charities would find it attractive, or indeed administratively possible, to continue to fund medical research in Scotland. Also, as other charity representatives pointed out, charitable funding is quite mobile and could move out of the country quite quickly, because it does not generally support infrastructure and indirect costs.

Although the level of charitable funding of medical research in Scotland is significant, the greatest impact on the research system could come from changes to the level of research council funding. The Scottish White Paper proclaimed that under independence, Scotland would continue to pay into the RCUK funding pot and draw funding from it on a competitive basis. In this context, Scotland and the rest of the UK

would be considered a single research area, but the UK government has claimed that Scotland would not have access to RCUK funds. This has caused great concern within the Scottish clinical community; however, our interviewees and workshop participants, including some research funders we talked to, suggested it would make no sense to contract the scale of UK research and lock Scotland out of the competitive funding steams. A number of salient points and scenarios were raised.

First, it would make sense for an independent Scottish Government to have various routes through to strategic medical research support; the ability not only to strategically control funds for local needs, but also to access open competition schemes, such as RCUK. One respondent stated: *'you could imagine a system where the main funding mechanisms of the research councils were open to Scotland and Scotland participated in them but there were various strategic schemes where Scotland has to either opt in or opt out and say we'll do something differently ourselves. It would be complicated but I don't think it would be impossible.'* (Senior Representative of Funding Agency 1)

Second, not only would the notion of a single research area benefit Scotland, it would also benefit the rest of the UK. As the funding agency representative went on to state, large competitive research systems are much better than smaller ones. Greater competition raises standards across the board and as systems get smaller and less competitive, other challenges arise. The respondent stated: *'Some countries with small funding streams find it harder to get international calibre external reviewers and … you also find that strategically smaller countries or smaller systems find it harder to stand back from current strengths and weaknesses and current vested interests, and plan in an open agile way for the future'.* On the other hand, some respondents stated that being part of a smaller system might enable greater strategic focus and differentiation from the rest of the UK, which provides both opportunities and challenges.

From a public funding perspective it would seem to make sense for an independent Scotland and the rest of the UK to continue to work together and share the infrastructure for competitive funding and maintain a single, coherent research area. As other respondents pointed out, the institutional and research cultures of the countries that comprise the UK are not particularly different and should be capable of working together for the benefit of all.

Interestingly, the notion of a single research area also has implications for commercial investment in clinical research. Our interviews with commercial organisations revealed that major pharmaceutical and device companies want to invest in a fairly homogenous system, so if the research area and funding mechanisms become too regionalised, this may impact on their investment strategies. Also, as some of our workshop participants stated, if Scotland were forced to do its own thing as part of a small, discrete research area, there is a risk that there would be a duplication of activities and infrastructure such that it might drive up the cost per clinical study and make it more expensive to do research compared to the rest of the UK. If the support and governance structures also became too different, cross-border collaborations might also be affected. (Some of our interviewees stated that cross-border collaborations sometimes already run in to difficulties under devolution.) International CROs are, according to our respondents, already concerned about future investments to a country that may not be part of the UK single research area.

It is not only medical and clinical research that can benefit from being part of a single research area. There is also an important implication of independence for the nature of medical training. A recent BMA Scotland paper[27] pointed out that the medical workforce is a mobile one, within the UK and internationally (14% of Scottish trained doctors moved abroad and 20% worked elsewhere in the UK). For this reason, it is important that medical education and training across the UK health systems is the same. The fear is that independence could lead to greater differentiation if Scotland reoriented its education system to meet the needs and requirements only of Scotland. Furthermore, the report questioned how medical practitioners would be regulated and governed in an independent Scotland. Regulation and governance is not limited to medical education, but also applies to regulation of medical research and new therapies. Would an independent Scotland have to set up its own regulatory agencies or could it contract with existing UK bodies? These are important questions for the debate.

Impact of Independence on Healthcare Priorities and Therapeutic Foci

The Scottish research and healthcare systems have undergone profound structural and organisational change since devolution. Parts of the system (NHS for example) are almost fully devolved, but other parts (the clinical and medical research – both commercial and non-commercial) are only partially devolved as they are far more closely integrated into broader UK initiatives and dependencies.

Indeed, much of the emphasis on translational public-private collaborations and getting the health services and key medical research assets linked together, which Scotland is institutionally and organisationally set up to exploit, is also occurring in this broader UK context. The NIHR, which is a UK resource, but mainly represents the interests of NHS England, alongside the TSB, is taking on these kind of activities in the context of driving forward stratified medicine programmes, and linking together large charities, particularly in cancer through Cancer Research UK, with genomics work and biorepositories. These activities raise questions about Scotland's capacity and future priorities under independence. Scotland does have some strong capabilities, and the geography, location and governance around key medical research and clinical assets contributes. Large concentrations of population near hospitals linked to medical schools create opportunities for research, but being linked into broader UK initiatives also has advantages, particularly access to funding.

There is perhaps a limit to what Scotland can achieve in exploiting the living lab concept due to the relative number and size of commercial companies operating in Scotland. Indigenous Scottish companies that carry out clinical studies, for example, are relatively small and, therefore, lack the capabilities to conduct large scale, market-focused clinical trials of the type that organisations, such as the TSB are promoting. This raises the question whether despite strong capabilities in both clinical studies and medical research, and good infrastructure and institutional assets that are well integrated, is Scotland too niche a player to fully exploit the potential of the living lab without linking with other UK players?

The potential loss of RCUK funding, or significant change in funding streams for clinical and basic medical research, will naturally affect how Scotland prioritises its research and

[27] BMA Scotland (2014) Independence Referendum 2014: Implications for Health: A Discussion Paper, James Mittra, Michele Mastroeni, David Wield, Elisabeth Barlow, Ken Snowden

the views of our interview respondents were mixed in terms of what the benefits and limitations might be. One representative from the NHS felt that the consequence might be that Scotland focuses far more on diseases where poverty and social deprivation were the major determinants, or perhaps in rare conditions where Scotland has a disproportionate population, such as MS or motor neurone disease. These are under researched disease areas that have a significant impact in Scotland. This would also enable studies based on the 'living lab' concept to flourish, as there would be the required level of disease burden. The benefits of a sick population are dependent on the condition and the outcome variables, as one of our clinical academic respondents stated. For example, lung cancer studies may be more efficiently conducted in deprived areas with heavy smokers and who have been inhaling industrial pollution for large parts of their life.

However, others felt that becoming too niche and losing more broad-based expertise in medical research might be to Scotland's ultimate detriment in terms of being a global leader in life sciences, for example. The question that needs to be asked, in this context, is what type of research system does Scotland ultimately want, and how will this fit with the current devolved healthcare system?

Summary and Conclusions

The key message from our research on the research and healthcare systems under devolution and potential independence is that Scotland is not so fundamentally different from the rest of the UK in terms of institutional assets, infrastructure, approaches and capacity. It has key strengths, but there is missing policy and economic evidence of what devolution, and potential independence, ultimately means for health and wealth. One key area of concern is the lack of clarity on post-independence funding structures, which will especially determine what can and can't be accomplished in medical research and healthcare delivery post-independence. Even if organisations, such as the CSO, have thought about it, they are not currently publishing their views. Neither have the major funding councils, although it is interesting to note that Scotland has historically been the most successful of the home nations in securing MRC funding – in 2008/09, it secured £64.7 million or 11.5%, even though it is home to only 8.5% of the population.[28] What is clear is that there are many different views about the benefits and limitations of the existing healthcare system and the complex research system that has evolved alongside it. In the public debate, emphasis has been very much on the fiscal and currency issues and where health has been discussed, it has been focused on the NHS and access to healthcare, with research very much marginalised.

In terms of key messages from our empirical work, we can summarise these as follows:

First, there is general agreement on basic issues, but a concern is that the research system and its role in healthcare have been missing from the actual debate. Research funding has simply been marginalised and there is a lack of recognition that a vibrant research system actively benefits the healthcare system.

[28] See http://www.hgu.mrc.ac.uk/news_section/news-articles_2010/S_Parliment_news_7.2010/MRC%20Funding%20in%20Scotland%20080610.pdf

Second, there are some clear dangers with independence: funding gaps, governance and its impact on strategic proprieties. But there are also opportunities to attract inward investment and improve both the research and health systems. However, one must question whether Scotland has sufficiently exploited all the powers of devolution. Our contention is that the living lab and the unique selling points of the Scottish medical research and innovation system offers an opportunity to attract commercial studies has not been fully realised under devolution. One issue has been the reluctance of the NHS to fully see itself as an integral part of the Scottish health innovation ecosystem. It is not clear that post-independence there would be any clear commitment or appetite to fully exploit the commercial potential of the science and clinical base. Delivery of patients into clinical trials is a clear opportunity on the clinical research side, and there are various innovative ways this could be done. For example, could Scotland undercut the competition on cost for clinical trials and perhaps radically change regulatory systems to maximise the translation of research into therapies? Commercial organisations need to see clear positives for investing in Scotland and a commitment to commercial health research. The White Paper does not outline these opportunities, which illustrates the lack of real support for commercial clinical research studies in Scotland. NHS and commercial organisations perhaps need to pull together and make sure they are mutually supportive if Scotland is to truly differentiate itself from the rest of the UK.

Third, independence would give greater flexibility to deal with social care. Medical research, on the other hand, may be worse off under independence. There is a real danger in acting locally and becoming insular. Nevertheless, Scotland could do new innovative things with its clinical infrastructure and research assets, and may be forced to if funding streams are fundamentally changed.

Fourth, there is still real uncertainty and potentially dangerous assumptions being made about currency and Scotland's place within Europe. Pragmatically, there is a risk that funding will go down, but opportunities to do things differently so long as strategies for long-term success are considered. There is, therefore, a need for vision and strategic planning for long-term exploitation of opportunities.

Finally, there is danger in the transition period to independence and it is clear from our research that we are already now in that uncertain transition period. Commercial organisations and collaborative research partnerships throughout Europe are reacting to the uncertain future of Scotland within the UK and Europe and this is having a material effect on the innovation system. For example, as one interview respondent from a funding body told us, if a Scottish research council was required, or indeed a regulatory agency, there is a risk that in the period of new institutional establishment short-term opportunities may be lost. Furthermore, in the period of transformation from being part of the UK to establishing a specifically Scottish strategy, many existing industry investments could pull out. The fear and concern generated during transition, and its impact on institutional and organisational behaviour, is a real and present danger.